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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09 704,212	10.31.2000	Wouter E. Roorda	M-9457 US	4669

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EXAMINER

MICHENER, JENNIFER KOLB

ART UNIT	PAPER NUMBER
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1762

DATE MAILED: 07/18/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/704,212

Applicant(s)

ROORDA ET AL.

Examiner

Jennifer Kolb Michener

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 23 June 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
- b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) ☐ they raise the issue of new matter (see Note below);
 - (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: see attached.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☐ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 2, 4-18, 20-22, 29-30.

Claim(s) withdrawn from consideration: _____.

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____.

ADVISORY ACTION

1. The reply filed June 23, 2003 fails to place this application in condition for allowance. The proposed amendments will not be entered because they raise new issues that would require further search and/or consideration. Additionally, they do not place the application in better form for appeal by reducing or simplifying the issues for appeal. Specifically, the limitation added to claim 29 requiring a specific order of process steps would require further search and/or consideration, not required by the searches conducted for the claim in its previous form. The proposed amendment to claim 29 to correct for the 112, 2nd requirement would be entered if submitted in a separate paper.

Response to Arguments

2. Applicant's arguments regarding the rejections maintained in this Office action have been carefully considered but they are not persuasive.

Applicant continues to argue that the new limitation "provided that the hemocompatible coating is not subjected to a dialdehyde cross-linking or stabilization step before in vivo use" is not new matter. It is argued that if Applicants are both silent about dialdehyde crosslinking and the disclosure teaches species that are incapable of cross-linking via a dialdehyde group, then a fair reading of the disclosure is that Applicants did not intend to teach any dialdehyde crosslinking.

Examiner disagrees. Contrary to Applicant's arguments, this limitation is not supported expressly, implicitly, or inherently. Applicant admits that "most" of the coatings of his invention don't have the primary amine necessary for dialdehyde crosslinking and such cross-linking would interfere with "virtually all" of Applicant's embodiments. Therefore, the coatings of Applicant do not preclude such crosslinking *in all cases*. Furthermore, even if none of Applicant's exemplary coatings contained primary amines, there would still be no basis for the newly added limitation. The exemplary teachings of some coatings that happen to contain no dialdehyde crosslinking do not provide basis for claiming all possible coatings with no such crosslinking.

Examiner notes that Applicant's disclosure may indeed be silent with regard to many process variables and limitations which Applicant did not intend to specifically require in the method of his invention. However, there is still no basis for claiming the absence of every process variable and limitation to which Applicant is silent.

Regarding Ex Parte Park, Examiner notes that in this case, two Wentworth declarations were cited to show that one of ordinary skill in that art would have recognized that the reaction of their disclosure is conducted without catalysts. Therefore, in this Park case, the specific reaction was inherently conducted in the absence of catalysts. This is not the case in the instant application. In fact, as outlined above, Applicant states only that "most" of the coatings of his invention don't have the primary amine necessary for dialdehyde crosslinking and such cross-linking would interfere with "virtually all" of Applicant's embodiments. In the absence of express, implicit, or inherent teaching of such a limitation, Ex Parte Grasselli is cited to teach that "the mere absence of a

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positive recitation is not basis for an exclusion". As outlined above, there are many process variables and conditions that are not specifically taught by Applicant's specification, but that does not mean there is a basis for claiming the absence of each.

Applicant argues that Hsu fails to teach that ethanol enhances the solubility of the heparin complex in the solution of the two solvents with the heparin and requests evidence to the contrary.

As outlined in the previous office action. Examiner notes that Hsu teaches coating PTFE substrates with the benzyl alkonium ion heparin in a fluoropolymer-wetting alkane solvent and an organic alcohol solvent, just as Applicant claims. Therefore, the organic alcohol solvent of Hsu inherently enhances the solubility of the heparin compound in the two solvents, just as it does in Applicant's invention. Additionally, Eriksson, which was used in the prior office actions as *evidence* of inherency, teaches that ethanol enhances solubility of such a heparin compound when used in combination with polar cyclohexane (col. 5). Ethanol inherently does the same in the method of Hsu.

Since Hsu teaches all of the limitations of the independent and applicable dependent claims, if there is some difference between Applicant's results and that of Hsu it must be due to some process limitation not claimed in the independent claims.

Applicant argues that the Eriksson in view of van Tassel rejection fails to teach the solvents listed in claim 30 because fluoropolymer-wetting cycloalkanes and fluoropolymer-wetting alkanes are mutually exclusive.

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Examiner disagrees.

Cycloalkane is a species within the genus of alkane. A fair interpretation of the original claims language is such that while cycloalkanes specifically were suitable solvents, so too were all alkanes, including straight-chained, branched, and cyclic. The presence of the cycloalkane species in a claim does not change the definition of alkane, the broader genus, to mean only linear or branched alkane.

Conclusion

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kolb Michener whose telephone number is 703-306-5462. The examiner can normally be reached on Monday through Thursday and alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shrive P. Beck can be reached on 703-308-2333. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.



Jennifer Kolb Michener
July 15, 2003



SHRIVE P. BECK
PAT. EXAMINER
JUL 15 2003
SUPERVISOR